

REMARKS/ARGUMENTS

Reconsideration is requested. Claims 1-12 are pending. Responsive to the Office Action of June 15, 2004, the Examiner's comments and the cited art have been noted and studied. For reasons to be set forth in detail below, it is respectfully submitted that the present application is in condition for allowance, and such action is requested.

Independent claims 1, 5 and 10 have been amended to clarify the presently claimed subject matter. In particular, claims 1, 5 and 10 have been amended to recite that the reagent pad is "underlying and adjoining" the aperture (support at, for example, FIG. 2 and FIG. 3 of the original disclosure). In this regard, Applicants trust that these amendments are responsive to the Office Action's suggestion that language should be used that better describes the reagent layer as being adjacent to and in physical contact as well as underlying the aperture (see page 7, paragraph 2 of the Office Action of June 15, 2004). In addition, claim 5 has been amended to correct a clerical error in the sequential lettering of the support member and reagent pad.

It is respectfully submitted that the amendments above are supported by the specification, claims, abstract of the disclosure, and drawings as originally filed, and that no new matter has been added.

35 U.S.C. §102 Rejections:

The subject matter of claims 1, 2 and 10 was rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,299,838 to Hirayama et al., (hereinafter "Hirayama").

Hirayama, as understood, describes a test apparatus that includes a cover with a sample-supplying hole, a reagent layer, and a support with a measurement hole therethrough (see, for example, col. 3, lines 29-55; col. 5, lines 56-60 and FIGs. 2-3 of Hirayama). Hirayama teaches that a detecting area of the reagent layer be covered by the cover (see col. 3, lines 53-55 and col. 5, lines 10-13 of Hirayama). Hirayama also describes and teaches that at least a portion of the cover that corresponds to the detecting area of the reagent layer be colored, for example colored yellow or black (see col. 3, lines 14-16; col. 4, lines 55-67 and col.5, lines 11-13 of Hirayama).

Independent claims 1 and 10, as amended, each recite the presence of “a reagent pad affixed to the support and underlying and adjoining the sample receiving aperture.” In addition, independent claims 1 and 10 recite that a portion of the support’s bottom surface “surrounding the aperture has a reflectivity of less than about 12 percent at between about 600 and 730nm” and that that portion, along with the aperture, correspond to an optical viewing area of an associated meter (claim 1) or colorimeter (claim 10). Hirayama does not describe, teach or suggest a test device or system as recited in amended claims 1 and 10. For example, Hirayama does not describe, teach or suggest that a reagent pad be affixed to a support such that the reagent pad **underlies and adjoins** a sample receiving aperture and that the sample receiving aperture and a surrounding portion of the support (which is of a specified reflectivity) correspond to an optical viewing area. Rather, Hirayama simply describes and teaches that a detecting area be covered by a colored cover. Furthermore, Hirayama teaches a reagent layer (element 3 in FIG. 1 of Hirayama) that is adjoining to a sample holding room (element 4 in FIG. 1 of Hirayama) and not the sample supplying hole (element 51 in FIG. 1 of Hirayama).

For at least the foregoing reasons, Applicants submit that the subject matter of amended claims 1 and 10 is neither anticipated nor obvious over Hirayama and allowable under 35 U.S.C. §102(e). Since dependent claims necessarily contain the limitations of their parents, dependent claim 2 is allowable for at least the same reasons.

The subject matter of claims 1-12 was rejected under 35 U.S.C. §102(b) as anticipated by U.S. No. Patent 5,843,692 to Phillips et al., (hereinafter “Phillips”). Phillips, as understood, describes a glucose assay device in the form of a strip with a reagent pad, hole and notch (see, for example, col. 9, line 44; col. 10, lines 61-65 and col. 11, lines 15-16 of Phillips).

The Office Action notes that column 15 of Phillips teaches a reflectance range of 1-100% that reads on 12%. Applicants respectfully submit that column 15 of Phillips appears to describe general equations for reflectance spectroscopy (e.g., equations (1), (2) and (3) of column 15) and merely notes that the equations hold for the range of no reflected light to total reflected light (see col. 15, lines 26-27 of Phillips).

There seems to be no description, teaching or suggestion in Phillips that a portion of a support’s bottom surface surrounding an “aperture has a reflectivity of less than about 12

percent at between about 600 and 730nm” and that that portion, along with the aperture, correspond to an optical viewing area of an associated meter. Rather, as understood, column 15 of Phillips merely presents equations and the general concept of no reflected light and total reflected light. There appears to be no suggestion that such general statements should be construed as indicating the desirability and benefits of employing a bottom surface surrounding an aperture with a reflectivity of less than about 12%.

For at least the foregoing reasons, Applicants submit that the subject matter of amended claims 1-12 is neither anticipated nor obvious over Phillips and allowable under 35 U.S.C. §102(b).

35 U.S.C. §103 Rejections:

The subject matter of dependent claims 3 and 11 was rejected under 35 U.S.C. §103(a) as obvious over Hirayama. Since dependent claims necessarily contain the limitations of their parents, dependent claims 3 and 11 are allowable for at least the same reasons as discussed above with respect to independent claims 1 and 10.

The subject matter of claims 3-9 and 11 was rejected under 35 U.S.C. §103(a) as obvious over Hirayama in view of Phillips. In this regard, Phillips was cited for sample volume and notch teachings.

Independent claim 5 recites a reagent pad that underlies and adjoins an aperture and that the aperture and portion of a bottom surface of a support correspond to an optical viewing area of a measuring instrument. As explained above with respect to claims 1 and 10, Hirayama does not describe, teach or suggest such a configuration. As further explained above, Phillips does not appear to describe, teach or suggest such a configuration or cure the deficiencies of Hirayama. Applicants, therefore, respectfully submit that the subject matter of amended claim 5 is not obvious over the cited combination of Hirayama and Phillips and is allowable under 35 U.S.C. §103(a).

Since claims 3-4, 6-9 and 11 depend from and further limit independent claims 1, 5, and 10, respectively, they are patentable for at least the same reasons.


CONCLUSION

Applicants respectfully request that, in light of the amendments and explanations above, the Examiner reconsider and withdraw his rejections. Applicants respectfully submit that the claims are in condition for allowance. In the event that minor claim amendments are necessary to meet formal requirements, Applicants invite the Examiner to telephone the undersigned so that issuance can be expedited.

The Commissioner is hereby authorized to charge any required fees due in connection with this submission, including petition and extension of time fees, and to credit any overpayment to Deposit Account No. 10-0750 (Docket No. LFS-123 US/MM) (Johnson & Johnson).

Respectfully submitted,

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